UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,261	02/18/2004	Louis E. Burton	39766-0037 C3C1	5841

25213 7590 07/16/2004

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CA 94025-3506

EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,261	BURTON ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040218*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF PRELIMINARY AMENDMENT, SEQUENCE LISTING, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. The preliminary amendment, the sequence listing, the Information Disclosure Statements (IDS) and Form PTO-1449 filed 2/18/04 are acknowledged, entered and considered. This is a Continuation of application Serial No. 10/072,681 filed 2/8/02, which is a Continuation of application Serial No. 09/675,503 filed 9/29/00, now U.S. patent No. 6,423,831, which is a Continuation of application Serial No. 09/363,573 filed 7/29/99, now U.S. Patent No. 6,184,360, which is Continuation of application Serial No. 08/970,865 filed 11/14/97, now U.S. Patent No. 6,005,081. In view of Applicant's request, the computer-readable form of the sequence listing of the parent application Serial No. 10/072,681, filed 2/8/02 has been transferred to the instant application Serial No. 10/782,261, filed 2/18/04 since the computer-readable form of the sequence listing of this application is identical to that in the parent application 10/072,681. Thus, in accordance with 37 C.F.R. 1.821(e), the computer-readable form of the sequence listing filed in the parent application has been entered and considered in the instant application. With respect to the IDS, the references cited therewith on Form PTO-1449 are not provided in the instant specification. However, as *per* Applicant's request, since the cited references were considered previously in parent applications Serial Nos. 10/072,681, 09/675,503 and 09/363,573; pursuant to 37 CFR § 1.98(d), the references cited in Form PTO-1449 in this application have been considered and signed as requested by Applicant. Claim 1 is present for examination.

OBJECTION TO THE TITLE OF THE INVENTION

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "ISOLATION OF NEUROTROPHINS FROM A MIXTURE CONTAINING OTHER PROTEINS AND NEUROTROPHIN VARIANTS USING HYDROPHOBIC INTERACTION CHROMATOGRAPHY"

HEADINGS FOR STATUTORY BASIS OF DOUBLE PATENTING

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

REJECTION UNDER 35 U.S.C. § 101 FOR DOUBLE PATENTING

4. Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,423,831. Both sets of claims are identical word for word. This is a double patenting rejection.

HEADINGS FOR NONSTATUTORY DOUBLE PATENTING

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

DOUBLE PATENTING-NONSTATUTORY WITH A PATENT

6. Claim 1 is rejected under the under the judicially created doctrine of double patenting over claims 2-22 of U.S. Patent No. 6,423,831.

The subject matter claimed in the instant application is set forth in the '831 patent claims. The patent and the application claim common subject matter, as follows: The instantly claimed invention and the patent claim a process to isolate a neurotrophin homolog from a mixture containing other proteins and variants of that neurotrophin homolog. The only difference between the '831 patent claims and the claim of the instant application is the scope of the claims in which the instantly claimed invention is limited to a neurotrophin homolog from a mixture containing other proteins and variants of that neurotrophin homolog while the '831 patent claims is broadly directed to a process to isolate a neurotrophin homolog from a mixture containing other proteins and variants of that neurotrophin homolog, recombinant neurotrophin and a composition thereof having various percentage homogenized to the sequence disclosed. Both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the scope of the claims and the disclosure of the isolation process with various resins and the amino acid sequences with percentages of homogenization thereof. The invention of the instantly claimed invention appears to be specific in scope than that of the '831 patent which is broader because the patent claims and/or encompasses the isolation of any kind of neurotrophin homolog using the various resins recited therewith and the disclosure of amino acid sequences with percentages of homogenization while the

instantly claimed invention claims only neurotrophin homolog from a mixture containing other proteins and variants of that neurotrophin homolog without claiming the amino acid sequences with percentages of homogenization and the various resins except a hydrophobic interaction chromatography resin. However, since both inventions are directed to a process of isolating neurotrophins; it is conventional and would be within the purview of ordinary skill in the art to use or adapt either the broader scope or the specific because both procedures use the same techniques for purification of neurotrophins as well as selecting the appropriate resins and percentages of homogenization of amino acids thereof. Therefore, both inventions are an obvious variation of the other since same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

DOUBLE PATENTING-NONSTATUTORY WITH A PATENT

7. Claim 1 is rejected under the under the judicially created doctrine of double patenting over claims 1-23 of U.S. Patent No. 6,184,360.

The subject matter claimed in the instant application is set forth in the '360 patent claims. The patent and the application claim common subject matter, as follows: The instantly claimed invention and the patent claim a process to isolate a neurotrophin from a mixture containing other proteins and variants. The only difference between the '360 patent claims and the claim of the instant application is the scope of the claims in which the instantly claimed invention is limited to a neurotrophin homolog from a mixture

containing other proteins and variants of that neurotrophin homolog while the '360 patent claims is broadly directed to a process to isolate a neurotrophin from mixture containing variants of said neurotrophin that can include a misfolded variant, an incorrectly proteolytically processed variant, and a glycosylated variant. Both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the scope of the claims and the disclosure of the isolation process with various resins and salt concentrations thereof. The invention of the instantly claimed invention appears to be specific in scope than that of the 360' patent which is broader because the patent claims and/or encompasses the isolation of any kind of neurotrophins using the various resins recited therewith while the instantly claimed invention claims only neurotrophin homolog from a mixture containing other proteins and variants of that neurotrophin homolog without claiming the various resins except a hydrophobic interaction chromatography resin. However, since both inventions are directed to a process of isolating neurotrophins; it is conventional and would be within the purview of ordinary skill in the art to use or adapt either the broader scope or the specific because both procedures use the same techniques for purification of neurotrophins as well as selecting the appropriate resins and salt concentrations thereof. Therefore, both inventions are an obvious variation of the other since same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

DOUBLE PATENTING-NONSTATUTORY WITH A PATENT

8. Claim 1 is rejected under the under the judicially created doctrine of double patenting over claims 1-25 of U.S. Patent No. 6,005,081.

The subject matter claimed in the instant application is set forth in the '081 patent claims. The patent and the application claim common subject matter, as follows: The instantly claimed invention and the patent claim a process to isolate a neurotrophin from a mixture containing other proteins and variants. Both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the scope of the claims. The invention of U.S. Patent No. 6,005,081 appears to be more specific in scope than that of the instantly claimed invention because the instant invention claims and/or encompasses the isolation of any kind of neurotrophin homolog from a mixture containing other proteins and variants of that neurotrophin homolog which may including recombinant while the '081 patent claims only recombinant human neurotrophins using the various resins recited therewith while the instantly claimed invention claims only neurotrophin homolog from a mixture containing other proteins and variants of that neurotrophin homolog without disclosing the various resins except a hydrophobic interaction chromatography resin. However, since both inventions are directed to a process of isolating neurotrophins; it is conventional and would be within the purview of ordinary skill in the art to use or adapt either the broader scope or the specific because both procedures use the same techniques for purification of neurotrophins as well as selecting the appropriate resins and salt concentrations thereof. Therefore, both

inventions are an obvious variation of the other since same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

PROVISIONAL REJECTION OF OBVIOUSNESS TYPE DOUBLE PATENTING

9. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/072,681, now allowed. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention (Serial No.10/072,681) is directed to a process to isolate a neurotrophin homolog from a mixture containing other proteins and variants of that neurotrophin homolog while copending application Serial No. 10/072,681 is directed to a process to isolate a neurotrophin from a mixture containing variants of said neurotrophins using specific purifying techniques and resins recited therewith. Both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the scope of the claims and the disclosure of the isolation process with specific purifying techniques and resins. The claim of the instant invention appears to be broader in scope than that of copending application which is specific because the copending claims and/or encompasses the isolation of neurotrophin using the specific resins recited therewith with specific purifying techniques while the instantly claimed invention claims broadly neurotrophins in general (i.e., any kind of neurotrophin) from a mixture

containing other proteins and variants of that neurotrophin without claiming the specific purifying techniques and resins recited therewith. However, since both inventions claim process of isolating neurotrophins and compositions thereof; it is an obvious variation to use or adapt either the broader scope or the specific scope because both procedures isolate neurotrophins. Therefore, both inventions are an obvious variation of the other since the same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other. Thus, absent of showing in the claim(s), it is apparent the isolation and/purifying neurotrophins and compositions thereof of copending application claims are an obvious variation of current claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and confusing in the recitation "containing onto" because it is not clear what the mixture containing onto? Amendment of the claim to recite "containing variants" is suggested.

Claim 1 is indefinite and inconsistent in the recitation "the variant" in last line because in line 2, recites "variants". Amendmentof the claim to recite "the variants" is suggested.

CONCLUSION AND FUTURE CORRESPONDENCE

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272-0955. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Jon P. Weber, Ph.D.
Primary Examiner

AAM Mohamed/AAM

July 12, 2004

JASEMINE C. CHAMBERS
DIRECTOR
TECHNOLOGY CENTER 1600